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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,419	11/12/2003	Jingkun Li	19596-0551 (45738-294417)	7609
23370	7590	12/01/2005	EXAMINER	
JOHN S. PRATT, ESQ KILPATRICK STOCKTON, LLP 1100 PEACHTREE STREET ATLANTA, GA 30309			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 12/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,419

Applicant(s)

LI, JINGKUN

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9, 10 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9, 10 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. The amendment submitted 15 September 2005 has been received. Claims 1-7, 9-10 and 20 are pending. Claims 8, 11-19 and 21-25 have been withdrawn.
2. All rejections not reiterated herein below are withdrawn in view of the amendment to the claims and/or arguments.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 9-10 and 20 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Noda et al (US 5,900,379) for reasons of record which are reiterated herein below.

Noda discloses a test kit comprising a lateral flow device having a section that is removable. The removable section comprises a capture region where immobilized antibodies are used to capture an analyte. See column 5, lines 35-44; and column 11, example 1.

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5. Claims 1-4, 7, 9, 10 and 20 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by LaBorde (US 6,607,922) for reasons of record which are reiterated herein below.

LaBorde discloses and immunochromatographic assay using superparamagnetic beads or particles coupled with antibodies to capture analytes in a sample. The particles are disposed on a test strip that can be removed from a support member for archival or analysis by appropriate means. See column 2, lines 5-15; column 3, lines 13-30; and column 4, lines 13-17. LaBorde teaches that the removable test strip is stable and can be achieved either before or after being read. The analytes contained in the capture zone remain there, labeled with the conjugate combination. See column 5, lines 48-63. Even though LaBorde does not specifically teach a test kit comprising such a device; labored anticipates the instant kit claim because it is nothing more than the device itself with no additional components.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over LaBorde in view of Benjamin et al (US 5,491,068).

See the discussion of LaBorde above. LaBorde differs from the instant invention in failing to teach growing the capture analyte in appropriate media.

Benjamin discloses a method comprising contacting a sample with magnetic solid support beads having antibodies immobilized thereon. If present, the target selected bacteria cells binds to the antibodies and the beads with attached immobilized bacteria are then washed to remove any remaining sample. The beads with the immobilized bacterial are spread on a culture medium and the bacteria are allowed to grow to form colonies. To confirm that the colonies are the bacterial of interest, the colonies are contacted with a colony lift membrane, and the membrane can be subjected to several detection/analytical procedures by which the presence or characteristics of the bacteria are determined. See column 4, lines 6-63.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to place the capture portion of LaBorde in a culture medium to increase the quantity of the analyte such as taught by Benjamin because Benjamin teaches that capture particles such as magnetic beads facilitate the capturing, isolating and enriching of microorganisms in order to accurately identify and study them, and a skilled artisan would have had a reasonable expectation of success in placing the capture portion of LaBorde in the grow medium taught by Benjamin.

Response to Arguments

8. Applicant's arguments filed 15 September 2005 have been fully considered but they are not persuasive.

Applicant argues that the instant claim differ from Noda and LaBorde because it recites that the detection zone is separated from other zones as well as the remainder of the device. Applicant argues that because Noda teaches that the result section is still attached to the cassette, therefore, Noda does not teach that the result section is separate or separable from the remainder of the device.

This argument is not persuasive. Noda teaches removing the sample collection zone as well as any other components of the cassette that otherwise prevent storage leaving just the detection zone. It is true that the detection zone is still attached to the cassette, however, because the cassette is removed from the casing, it is seen to meet the limitation that the detection zone is removed from the remainder of the device, i.e. the casing. In other words, the device of the instant invention is not limited to the backing strip. Since the claims do not recite that the detection zone is free of all other components, such as sample receiving zone, conjugate zone, overflow zone or backing strip, only that the detection zone is separate from other zones and the "remainder" of the device, the casing taught by Noda is seen to be the same the "device" of the instant invention. Therefore, removal of the cassette comprising only the detection zone anticipates claims 9, 10 and 20.

Applicant also argues that the amended claims recite that the detection zone is separated from the other zones as well as the remainder of the device and that these claims differ from LaBorde because LaBorde does not teach the separation of the detection zone from the other zones of the device.

This argument is not persuasive. LaBorde teaches the removal of the test strip from the support member as well as the removal of other zones such as sample pad and wicking pad. See column 5, lines 25-39. Therefore, LaBorde anticipates the instant claims.

Applicant's arguments with respect to the rejection of Benjamin in view of Whitehead have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and


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any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641
11/26/05